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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1638	8

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/811,050	STELPFLUG, DICK	
	Examiner	Art Unit	
	Medina A Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *15 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants' response filed 10/15/02 in reply to the Office action mailed 06/04/02 have been entered. Claims 19 and 20 are newly added. Therefore, claims 1-20 are pending and are under examination.

This Office action contains NEW GROUNDS OF REJECTIONS not necessitated by Applicant's amendments. Therefore, this action is non-final. The delay in applying these grounds of rejection is regretted.

All rejections and objections not stated below have been withdrawn. The objection to the specification and to claims 1, 6, and 9 for failing to recite ATCC accession number is withdrawn in view of Applicant's statement that the deposit ATCC accession number will be provided upon allowance of the claims.

Claim Objections

Claim 6 (first claim 6) is objected to because it is misnumbered. Claims 6 has been renumbered ---claim 5---, as per rule 37 CFR 1.126. ***Claim Rejections - 35 USC § 112, 2nd paragraph***

1. Claims 4-5 and 8-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is noted that some of the claims recite corn while others recite maize or both maize and corn. It is suggested that all claims recite either corn or maize, for consistency in claim language.

In claim 4, "the cells or protoplasts of the tissue" lacks proper antecedent basis. It is suggested that the phrase is replaced with ----wherein the tissue culture is prepared from a tissue----.

In claim 5, "capable of expressing" implies that the plant may or may not express all of the physiological and morphological characteristics of the inbred. It is suggested that "capable of expressing" be replaced with ---having---.

Claim 9 is indefinite in the recitation of "using" without any positive method steps. In part (c), "provide" should be replaced with ---produce---, to provide antecedent basis for the phrase "said non-pollen producing inbred" recited later in the claim

In claims 10 and 11, "the regenerable cells" lack antecedent basis. It is suggested that "the regenerable cells of" is replaced with ---regenerable cells from---.

In claims 14 and 17, a coma should be before the second "at least"; also a transgene "capable of being identified" in claim 14 is unclear.

Claims 15 and 16 remain rejected, because it is unclear how the mutant gene was acquired by the plant. Since the instant rejection is one of indefiniteness and not one of lack of written description, Applicants' arguments that both gene mutations and mutant transgene are well known in the prior art and are adequately described in the specification are not persuasive. In addition, the metes and bounds of "said mutant gene being a mutant gene relative to the genes in the plants resulting from growing the representative seed deposited in claim 1" are unclear as there are not known genes resulting from growing the seed.

In claim 18, "the steps" should be replaced with ---the method---, for proper antecedent basis. Also, "said selected plants" should be changed to ---to produce selected plants----.

In claim 19, what is encompassed in the additional step is unclear. Also, the metes and bounds of "biological techniques wherein identifying the seed as an inbred seed" is unclear. Also, "comprising additional step" should be changed ---further comprising---.

Claim Rejections - 35 USC § 112, Ist paragraph, deposit requirement

Claims 1-20 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reasons of record as set forth in the Office action mailed 06/04/02.

In the response of 10/15/02, Applicants state that a deposit of the seed of the inbred line G3001 will be made and requested withholding the deposit requirement until the claims are allowed (response, p.1). However, deposit of the inbred line G3001 is required to overcome the rejection.

Claim Rejections - 35 USC § 112, Ist paragraph, enablement

Claims 12-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims 12-17 are broadly drawn to corn plants/seeds of the inbred line G3001 comprising at least one transgene or mutant gene, hybrid plant/seed comprising at least one transgene or one mutant gene produced by hybrid combination of plants of the inbred line G3001 and plants "derived from " or plants having at least "one ancestor" being G3001.

Applicant has not disclosed or provided guidance for a plant or seed of the inbred corn line G3001 or hybrid plants/ seed thereof comprising at least one transgene "capable of being identified" or at least one mutant gene, wherein said gene is transferred by breeding techniques. No guidance has been provided for the obtention of F1 or other hybrid plants/seed comprising a transgene or mutant gene from a parent plant. In addition, no guidance has been provided for the introgression of any trait from a multitude of non-disclosed and uncharacterized parentals into the claimed variety, wherein said introgression should result in successful expression of the desired trait but should not interfere with expression of the remaining traits whose combination confers patentability to the instantly exemplified variety, and which introgression should not introduce unwanted linked genetic material into the exemplified cultivar which would disrupt its patentably unique genetic complement. The prior art does not amend the deficiency. In addition, Applicant has not provided guidance regarding the genetic or the morphological characteristics of any of the breeding partners, or the resultant progeny.

While transformation of plants with specific transgene for a desired trait by genetic engineering may be within the level of one skilled in the art, the state of the art

teaches that it is unpredictable whether a gene or genes for conferring a phenotype in one plant genetic background may be transferred into the genetic background of another plant to confer the phenotype in said different plant. For example, Hunsperger et al (US Patent No. 5, 523, 520) disclosed a specific gene trait in the genetic background of one plant which has been introgressed into the genetic background of another plant of the same species, that didn't result in the expected transferred gene trait (column 3, lines 26-46). Kraft et al (Theor. Appl. Genet. 2000, vol. 101, pp. 323-326) teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single transferred trait, and such that effects are unpredictably genotype specific and loci dependent in nature. Kraft et al teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding material, and therefore, is an unpredictable effect in plant breeding (page 323, column 1, line 7 to line 15). See, Eshed et al (Genetics, vol. 143, pp1807-1817, 1996) who teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). Neither the instant specification nor the prior art provides evidence that such linkage disequilibrium, linkage drag, or epistatic effect are not common in corn breeding materials, such that one or more transgenes can be transferred from one genetic background to another.

In addition, the specification does not provide specific guidance for how the transgene is introduced in the plant. The state of the art teaches unpredictability inherent in the transformation of plants to obtain desired phenotype. For example, see Napoli et al (The Plant Cell, Vol. 2, pp. 279-289, 1990) who teach the introduction of a transgene (chalcone synthase) into a plant that did not result in the expected desired trait in the plant (see page 279, Abstract). Therefore, absent specific guidance, one skilled in the art is left with trail and error experimentations considered to be undue.

Regarding claims 18 and 19, the claims remain rejected as the specification is not enabling for a method for identifying the inbred corn seed G3001 because the specification does not disclose a repeatable process that one skilled in the art can use to reproduce the exact the same seed of G3001. Applicants believe that the rejection will be obviated upon deposit of the seed. However, the deposit of the seed will not overcome the rejection because the claims are not drawn to the seed itself but to a method for identifying the seed, for which there is not sufficient guidance provided in the instant specification.

Therefore, given the lack of guidance in Applicants' specification regarding transfer and expression of genes by backcrossing in Applicant's corn line while retaining the other desirable genotypic and phenotypic characteristics, the lack of guidance regarding the isolation of a multitude of non-exemplified transgenes or their evaluation in particular corn genetic backgrounds, the state of the art, the unpredictability inherent in single gene transfer, and lack of working examples, one skilled in the art would not be able to make and/or use the invention, without undue experimentations.

Written Description

Claims 6-17 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Office action mailed 06/04/02. Applicants' arguments filed 10/15/02 have been fully considered but are not deemed persuasive.

The claims are broadly drawn to any hybrid corn plant /seed produced by crossing the exemplified inbred line of G3001 or plants "derived from" or a plant comprising "at least one ancestor being G3001" with plants of another corn lines as well as hybrid seed and plants comprising at least "one ancestor" being the inbred corn plant G3001. The claims encompass any hybrid plant/seed produced by crossing G3001 plant with any of a multitude of non-exemplified plants, or any descendant of the exemplified cultivar obtained by using that cultivar as one parent in a series of undisclosed crosses for an undisclosed number of generations and with undisclosed breeding partners. These are genus claims. Applicant only describes inbred corn line G3001 having a specific combination of genotypic and phenotypic characteristics that distinguish the line from other corn lines. Applicant has not described the morphological and/or genotypic characteristics for all hybrid corn plants and seeds of claims 6-11 produced by crossing the inbred corn line G3001 with another unidentified corn plant. No specific morphological or genotypic characteristics that distinguish F1 hybrid corn

plants/seeds from other corn plants and seeds are described. Applicant has not described the breeding partners involved in crossing with the exemplified plant, or the resultant product. Since Applicant has not described even F1 generation plants/seed, plants of subsequent generations of claims 7-8, 14 and 17 are similarly not described. Note that claims 7-8, 14 and 17 are not limited to F1 hybrids.

Regarding claims 12-17, the claims remain rejected because Applicant has not described any and all transgenes or mutant genes or their phenotypic effects in particular corn genetic background. In addition, the claims do not characterize the sequence or identity of the transgenes or recite phenotypic effects.

Accordingly, the claimed invention lacks adequate written description as required under the current written description guidelines (See Written Description Requirement published in Federal Registry/Vol.66, No. 4/Friday, January 5, 2001/Notices; P. 1099-1111).

Response to Arguments

Applicants argue that the claimed hybrid plants and seeds meet the written description requirement because the biological material that is G3001 is to be deposited and that one skilled in the art knows how to identify the basic genetic footprint of G3001 in a pedigree (p. 4 of the response). Applicants also argue that the genetic fingerprint of the deposited material can be determined and then used to identify portions of the G3001 genetic fingerprint in the hybrid combination and/or descendents which have G3001 as an ancestor or having G3001 as a parent in the hybrid seed in their pedigree, without undue experimentation (p. 6, 2nd and 3rd full paragraphs). Applicants assert that

methods for tracking pedigree through marker-assisted breeding are well known by those skilled in the art. Applicants further argue that table 4 of the specification shows the line G3001 in 26 different hybrids combinations and that at the time of the invention the applicant possesses at least 30 million hybrid seeds having an ancestor of G3001 (p. 5 of the response). Applicants assert that the use of G3001 as an ancestor is within the parameters of what is expected by the ordinary plant breeder (p. 6 of the response). Applicants urge that given the data in the specification that shows inventors were in possession of at least 30 million examples, and the various breeding methods for tracking pedigree and numerous markers approaches which are in standard use in the maize industry, written description requirement is satisfied. Therefore, Applicants urge that the rejection be withdrawn.

The Examiner maintains that the rejection is proper given that the claimed hybrid plants and seeds are not adequately described. Firstly, while the deposit of the seed of inbred line G3001 is sufficient to provide written description for F0 generation plants/seed, the deposit is insufficient to provide adequate written description for any hybrid plant or seed including F1 generation or those comprising at least "one ancestor" or "derived from" the inbred line G3001. Applicant has not indicated that any hybrid progeny obtained from the inbred line G3001 will also be deposited. In addition, while the corn plant/seed of the inbred line G3001 has been described in the specification by some phenotypic characteristics, no description of the genetic material in the genome of the corn plant/seed of the inbred line G3001 has been described. No markers that can be used to identify genetic fingerprinted in G3001 have been disclosed. Applicant has

not described gene sequences or molecular markers that distinguish the genetic material of the G3001 corn plants from the genetic material of other corn plants. No phenotypic traits that are highly inheritable in G3001 have been described. Therefore, Applicants' arguments regarding the deposit of the inbred line G3001 seed, and the use of markers to track G3001 parental lines does not address the lack of written description throughout the broad scope of the claims.

With respect to Table 4, it is noted that the disclosed hybrid plants/seed are only F1 hybrid plants and are only described by some physiological characteristics such as percent root or percent stalk lodge, moisture, or yield. Such physiological characteristics are insufficient to provide identifying characteristics that distinguish the claimed hybrid plant from other hybrid plants. In addition, the claimed plants are neither limited to F1 generation plants, nor to 26 different hybrid plants nor to a few non-G3001 parental lines as breeding partners. The claims are broadly drawn to any hybrid plant /seed produced by crossing the exemplified inbred line or plants "derived from" with any of a multitude of non-exemplified plants, or any descendant of the exemplified cultivar obtained by using that cultivar as one parent in a series of undisclosed crosses for an undisclosed number of generations and with undisclosed breeding partners. In addition, since the phenotype of a hybrid plant is contributed by both parents involved in the crossing, each of the hybrid plant/seed produced from a cross with G3001 or a plant "derived from" G3001 may be phenotypically distinct. Therefore, substantial variation in structure and phenotypes is expected even among F1 hybrid plants. Therefore, a description of the phenotypic characteristics of one parent plant is insufficient to

describe any hybrid plant /seed produced from hybrid combination of plant of the inbred line G3001 and another corn plant, even if 30 million seeds/plants are produced from 26 different hybrid combinations.

With respect to *Eli Lilly,* the Examiner maintains that the case law is applicable, especially where the court stated that to adequately describe a claimed genus, Applicant must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of members of the genus". Id. In the instant application, Applicant has not described a representative number of species of the claimed genus because substantial variation in structure and phenotypes are expected among the resultant hybrid plants as discussed above.

Regarding the rejection to claims 12-17, Applicant has not described a multitude of non-exemplified transgenes or their phenotypic effects in particular corn genetic backgrounds. In addition, the claims do not characterize the sequence or identity of the transgenes or recite phenotypic effects, and therefore, one skilled in the art would know Applicants were in possession of the invention as broadly claimed, at the time application was filed.

Accordingly, for all the reasons discussed above, the written description requirement is not satisfied. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 102/103

Claims 6-11, 14 and 17 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Buendgen (US 5, 866,

763). The rejection is maintained for the same reasons as set forth in the Office action mailed 06/04/02. Applicant's arguments filed 10/15/02 have been fully considered but are not found persuasive.

Applicant's argue that the invention in claims 6-11, 14 and 17 require that G3001 be in the pedigree of the descendents and that the invention by Buendgen does not suggest lines that have G3001 as an ancestor. Applicants urge that, since the patent to ZS01220 does not teach or suggest G3001 as a breeding tool, the rejection should be withdrawn (response, p. 9).

The Examiner maintains that the rejection is proper given that the claims are broadly drawn to any hybrid seed or plants, including F1 generation plants, produced by a cross between the corn plant of the inbred line G3001 or plants "derived from" it or plants having "at least one ancestor being G3001" with another unknown corn plant, wherein the resultant plants have no disclosed phenotypic characteristics (see Written Description rejection above).

In response to Applicants' argument regarding the features of the G3001 that the prior art plant fails to disclose, it is noted that said features are not recited in the rejected claims, and there is evidence showing that said features are transferred to all progeny of the G3001 line. As stated above (Written description rejection), the claimed hybrid plants and seeds may have any combination of characteristics. A cross between plant of the inbred line G3001 and any second corn variety will result in hybrid plant with wide range of phenotypic characteristics, and it appears that the prior art corn plant falls within this range. In addition, it should be noted that the claims are rejected under

102/103 because the Examiner cannot determine whether the prior art plant possesses the unrecited features. The Examiner does not have sufficient facts to determine whether the corn plant and seeds are inherently the same. In addition, the Examiner cannot conclude that the claimed subject matter would have been obvious since it cannot be determined whether the corn plants differ. Applicants' arguments do not provide clear and convincing evidence that the prior art would neither anticipate nor render obvious the claimed invention. See *In re Thorpe,* 227 USPQ 964, 966 (Fed. Cir. 1985).

Claims 1-5, 12-13, 15-16 and 18-20 are deemed free of the prior art of record.

Remarks

No claim is allowed.

Papers related to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmission 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday-Thursday from 8:30AM to 5:30PM and every other Friday 9:00AM to 5:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

23/12/02
Mai

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